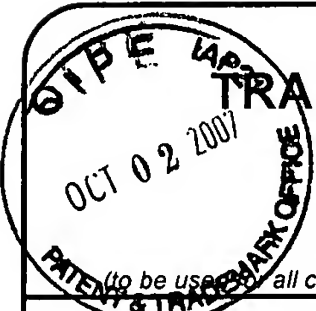



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 <b>TRANSMITTAL FORM</b> (to be used for all correspondence after initial filing)	Application Number	10/691,823	
	Filing Date	October 23, 2003	
	First Named Inventor	David Grewe et al.	
	Art Unit	3736	
	Examiner Name	J. Hoekstra	
Total Number of Pages in This Submission	24	Attorney Docket Number	25647-410611

ENCLOSURES (Check all that apply)		
<input type="checkbox"/> Fee Transmittal Form <input type="checkbox"/> Fee Attached <input type="checkbox"/> Amendment/Reply <input type="checkbox"/> After Final <input type="checkbox"/> Affidavits/declaration(s) <input type="checkbox"/> Extension of Time Request <input type="checkbox"/> Express Abandonment Request <input type="checkbox"/> Information Disclosure Statement  <input type="checkbox"/> Certified Copy of Priority Document(s) <input type="checkbox"/> Reply to Missing Parts/Incomplete Application <input type="checkbox"/> Reply to Missing Parts under 37 CFR 1.52 or 1.53	<input type="checkbox"/> Drawing(s) <input type="checkbox"/> Licensing-related Papers <input type="checkbox"/> Petition <input type="checkbox"/> Petition to Convert to a Provisional Application <input type="checkbox"/> Power of Attorney, Revocation Change of Correspondence Address <input type="checkbox"/> Terminal Disclaimer <input type="checkbox"/> Request for Refund <input type="checkbox"/> CD, Number of CD(s) _____ <input type="checkbox"/> Landscape Table on CD	<input type="checkbox"/> After Allowance Communication to TC <input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences <input type="checkbox"/> Appeal Communication to TC (Appeal Notice, Brief, Reply Brief) <input type="checkbox"/> Proprietary Information <input type="checkbox"/> Status Letter <input checked="" type="checkbox"/> Other Enclosure(s) (please identify below): Amended Brief in Response to September 21, 2007 Notification
<div style="border: 1px solid black; padding: 5px; min-height: 100px;">           Remarks         </div>		

## SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm Name	Seyfarth Shaw LLP		
Signature			
Printed name	George H. Gerstman		
Date	Sept. 26, 2007	Reg. No.	22,419

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE  
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES  
(Docket No. CRD1061 CIP1)

In re the Application of:	)	<b>Customer No. 27717</b>
	)	
David Grewe et al.	)	
	)	<b>Group Art Unit: 3736</b>
Serial No.: 10/691,823	)	
	)	
Filed: October 23, 2003	)	<b>Examiner: J. Hoekstra</b>
	)	
For: Guidewire with Deflectable Tip	)	
Having Torque Characteristics	)	

TO: MAIL STOP: Appeal Brief-Patent  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, Virginia 22313-1450

**APPEAL BRIEF**

Dear Sir:

This is the Appeal Brief for the appeal filed on June 21, 2007. Please charge Deposit Account No. 19-1351 of Seyfarth Shaw LLC for the appeal brief fee and any added fees that may be required.

**I. REAL PARTY IN INTEREST**

The real party in interest is Cordis Corporation, the assignee of this application. Cordis Corporation is a subsidiary of Johnson & Johnson.

**II. RELATED APPEALS AND INTERFERENCES**

There are no prior or pending appeals, interferences, or judicial proceedings known to Appellant, the Appellant's legal representative, or the assignee, which may be related to, directly affecting, or be directly affected by or having a bearing on the Board's decision in this appeal.

### III. STATUS OF CLAIMS

Claims 1, 3-19, 21-23 and 25-37 are rejected, and comprise the claims on appeal.

Claims 2, 20 and 24 were canceled.

Claims 38 and 39 were cancelled (by amendment filed August 16, 2007).

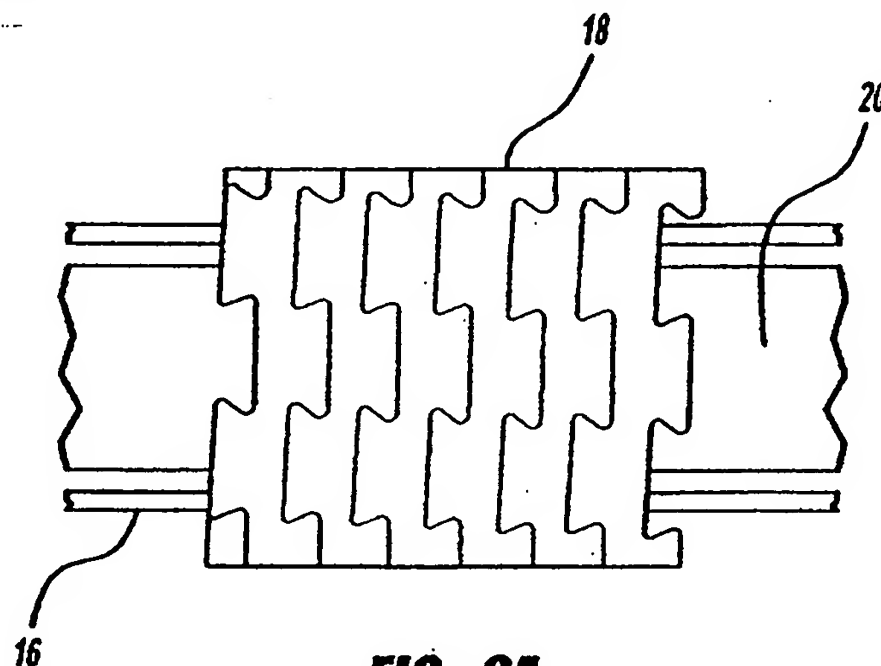
### IV. STATUS OF AMENDMENTS

The amendments are as they stand in the Amendment filed December 29, 2006 and the amendment filed August 16, 2007.

### V. SUMMARY OF CLAIMED SUBJECT MATTER

#### A. Subject Matter of Independent Claim 1

Claim 1 concerns a bi-directional steerable guidewire 12 having a deflectable tip (p. 6, lines 13-17). The guidewire of claim 1 comprises an elongated flexible tubing 16. A flexible helical coil 18 (Figs. 2 and 2A) is provided (p. 6, line 16). The helical coil 18 has a rectangular cross-sectional configuration and has continuous undulations (See Fig. 2A and p. 8, lines 20-25). The undulations of adjacent turns interlock with each other in order to enhance the rotational rigidity of the coil (p. 3, line 19 – p. 4 line 3; Fig. 2A reproduced below). Also see p. 8, line 20 – p. 9, line 2.

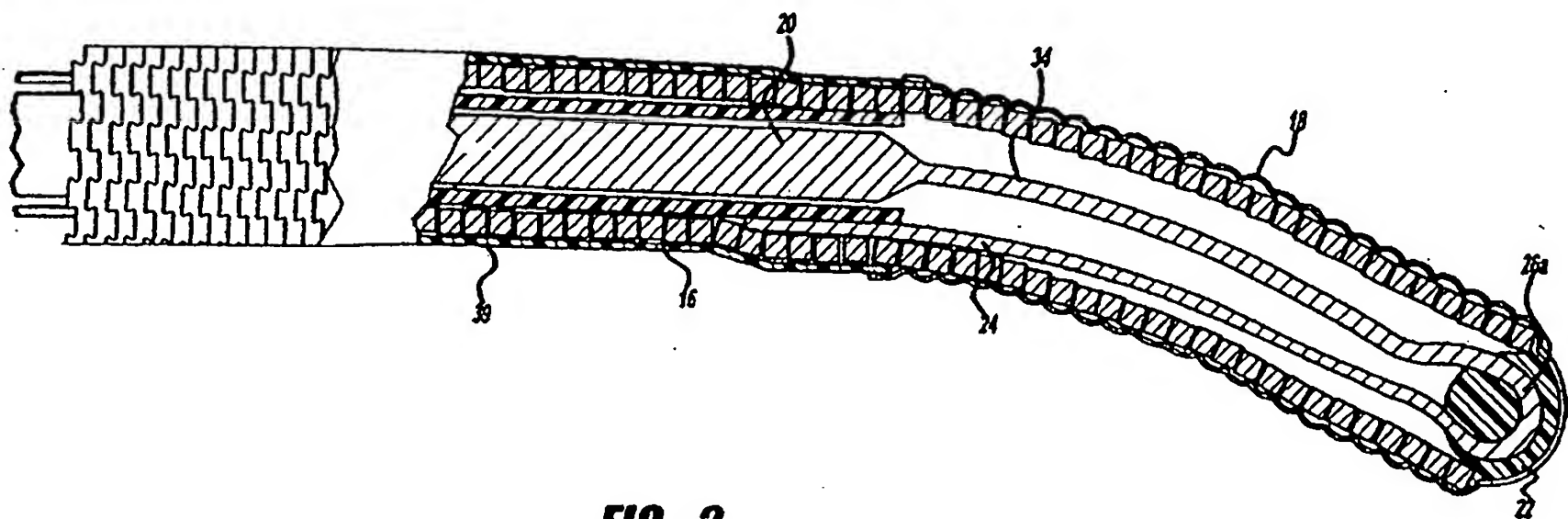


**FIG - 2A**

The undulations of helical coil 18 are lateral to the length of the elongated flexible tubing 16. The undulations take the form of a sinusoidal wave having positive and negative peaks. The positive peaks of adjacent turns of coils engage negative peaks of adjacent turns of coils (p. 4 lines 15-18; Fig. 2A).

As pointed out in the specification, the interlocking turns formed by the undulations enhance the rotational rigidity or "torqueability" of the coil 18. In this manner, the distal end of the coil more nearly tracks, rotationally, the proximal end of the coil, thereby significantly improving the tortional characteristics of the coil. By improving the tortional characteristics of the coil, the overall tortional characteristics of the guidewire are significantly improved (p. 8 line 20 – p. 9 line 6).

Continuing with the subject of claim 1, an elongated deflection member 20 is also provided. Deflection member 20 is slidably disposed within the tubing 12 and within the helical coil 18. The distal portion of the deflection member 20 is flattened (see Fig. 2) to form a deflection ribbon 34 which extends in a plane (p. 7 lines 15-18).



**FIG - 2**

A retaining ribbon 24 is also provided the proximal end of the retaining ribbon 24 is attached to the distal portion of the flexible tubing and the retaining ribbon is oriented to extend in a plane which is generally parallel to the plane of the deflection ribbon 34 (p. 7 lines 23-24).

An attachment member 22 engages the distal end of the helical coil 18, the distal portion of the deflection member 20 and the distal end of the retaining ribbon 24 (Figs. 2-4). In this manner, longitudinal movement of the deflection member 20 in a distal direction causes the distal end of the helical coil 18 to be deflected in one direction and longitudinal movement of the deflection member 20 in a proximal direction causes the distal end of the helical coil 18 to deflect in another opposite direction (p. 7, lines 6-10; p. 9, lines 17-22).

#### **B. Subject Matter of Independent Claim 19**

Claim 19 concerns a steerable guidewire 12 having a deflectable tip (p. 6, lines 13-17). An elongated flexible member forms the steerable guidewire 12. A flexible helical coil 18 is provided, having multiple turns. (Figs. 2 and 2A).

The helical coil 18 has a rectangular cross-sectional configuration and has continuous undulations (p. 8, lines 20-25). The undulations of adjacent turns interlock with each other in order to enhance the rotational rigidity of the coil. (Fig. 2A and p. 8, lines 20 – p. 9, line 2). The undulations are lateral to the length of the elongated flexible member which forms the steerable guidewire. The undulations take the form of a

sinusoidal wave having positive and negative peaks (p. 4, lines 15-17). The positive peaks of adjacent turns of coils engage negative peaks of adjacent turns of coils (p. 4, lines 17-18). A proximal end of the helical coil is attached to the distal portion of the elongated flexible member (p. 7, lines 14-15).

A rounded bead 22 engages the distal end of the helical coil of the steerable guidewire (p. 7, lines 2-5).

### **C. Subject Matter of Independent Claim 23**

Claim 23 concerns a steerable guidewire 12 having a deflectable tip (p. 6, lines 13-17). An elongated flexible tubing 16 is provided. A flexible helical coil 18 is provided having multiple turns (Figs. 2 and 2A). Helical coil 18 has a rectangular cross sectional configuration and has continuous undulations (p. 8, lines 20-25). The undulations of helical coil 18 of adjacent turns interlock with each other in order to enhance the rotational rigidity of the coil. (Fig. 2A and p. 8, line 20 – p. 9, line 2). The proximal end of the helical coil is attached to the distal portion of the flexible tubing (p. 7, lines 14-15).

The undulations take the form of a sinusoidal wave having positive and negative peaks (p. 4, lines 15-17). The positive peaks of adjacent turns of coils engage negative peaks of adjacent turns of coils. (Fig. 2A and p. 4, lines 17-18).

An elongated deflection member 20 is provided (p. 6, line 25). The deflection member 20 is slidably disposed within the tubing and within the helical coil 18 (p. 6, line 26 – p. 7, line 3). The proximal portion of the deflection member 20 is of cylindrical cross section (p. 7, lines 16-17). The distal portion of the deflection member takes the form of a deflection ribbon which extends in a plane (p. 7, lines 15- 21).

A retaining ribbon 24 is provided. The proximal end of retaining ribbon 24 is attached to the distal portion of the flexible tubing (p. 7, lines 21-24). The retaining ribbon is oriented to extend in a plane which is generally parallel to the plane of the deflection member 20 (p. 7, lines 21-24).

An attachment member 22 is provided (Fig. 2). The attachment member engages the distal end of the helical coil 18, the distal portion of the deflection member 20 and the distal end of the retaining ribbon 24 (p. 7, lines 1-5). In this manner, longitudinal movement of the deflection member 20 in a distal direction causes the distal end of the helical coil 18 to be deflected in one direction. Longitudinal movement of the deflection member 20 in a proximal direction causes the distal end of the helical coil 18 to deflect in another opposite direction (p. 7, lines 6-10; p. 9, lines 17-22).

## **VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL**

Whether claims 1, 3-19, 21-23 and 25-37 were properly rejected under 35 U.S.C. §103(a) as being unpatentable over Hayzelden et al. U.S. 2002/0165534 in view of Klima et al. U.S. Patent No. 6,273,876.

## **VII. ARGUMENT**

### **A. The Rejection of Claims 1, 3-18, 23 and 25-37 as Obvious over Hayzelden et al. in view of Klima et al. Should Be Reversed.**

The references applied by the Examiner are inapplicable to the invention as claimed. First, neither Hayzelden et al. nor Klima et al. concern a guidewire. Guidewires are used to facilitate the insertion of a catheter into a vessel of the body. A guidewire typically has a closed distal end and when it is inserted into a vessel, a catheter is introduced over the guidewire. The catheter is moved through the vessel

until the distal end of the catheter is positioned at a desired location. The guidewire is then retracted from the catheter and the catheter is left in the vessel.

Often guidewires are used for removing an obstruction within a vessel, using the closed distal tip of the guidewire. Ordinarily the guidewire is inserted within the vessel, the distal tip of the guidewire is moved into contact with the obstruction and then the distal tip of the guidewire is tapped against the obstruction until the guidewire passes through the obstruction.

The present invention provides a guidewire having a steerable tip in order to facilitate movement of the guidewire through the tortuous vessels of the body. The benefit of the present invention is that the guidewire having a very small diameter has very precise steering, as a result of the structure set forth in Appellants' claims. The references applied by the Examiner do not teach the structure as claimed.

First, Hayzelden et al. does not disclose a "steerable guidewire." Instead, Hayzelden et al. concerns an ablation catheter having electrodes and used for an entirely different purpose. Hayzelden et al.'s ablation catheter is used to destroy certain heart tissue causing an arrhythmia, by applying RF energy to the conductive tissue. Hayzelden et al.'s ablation catheter thus serves an entirely different purpose, is structurally different, and the distal end of Hayzelden et al.'s catheter accesses an area of the heart that is different from the area of the vessel where Appellants' guidewire is positioned.

In the final rejection, the Examiner states that Hayzelden et al. teaches a bi-directional steerable guidewire. This is simply incorrect. As stated above, Hayzelden et



al. concerns an ablation catheter and there is no disclosure or even a suggestion within Hayzelden et al. of a steerable guidewire.

In paragraph 24 of the final rejection, the Examiner states that the recitation of a bi-directional steerable guidewire “has not been given patentable weight because the recitation occurs in the preamble.” The Examiner’s statement is incorrect because the “steerable guidewire” is expressly referred to twice in the body of independent claims 1 and 23. To disregard the term “steerable guidewire” even though it appears within the body of the claims as well as in the preamble is clearly erroneous.

Appellants’ claims call for “a flexible helical coil having multiple turns.” Hayzelden et al. does not disclose a flexible helical coil. Instead, Hayzelden et al. discloses a wire braid which is structurally and functionally significantly different from a helical coil.

In the final rejection, the Examiner erroneously states that Hayzelden et al. teaches a flexible helical coil (82) having multiple turns. Appellant had previously advised the Examiner that Hayzelden et al. does not teach a flexible helical coil, but while the Examiner mentioned this argument by Appellant, the Examiner failed to provide any meaningful response thereto.

It is apparent that the Examiner’s statement that Hayzelden et al. has a flexible helical coil (82) having multiple turns has no basis whatsoever and is clearly erroneous. The specification of Hayzelden et al. makes it very clear that middle layer 82 of Hayzelden et al., referred to by the Examiner, comprises braided ribbons, which are completely different in structure from a helical coil.

Claims 1 and 23 also require that the helical coil has a rectangular cross-sectional configuration and has continuous undulations wherein the undulations of adjacent turns interlock with each other. Claims 1 and 23 further state that the undulations take the form of a sinusoidal wave having positive and negative peaks and in which the positive peaks of adjacent turns of coils engage negative peaks of adjacent turns.

In paragraph 20 of the final rejection, the Examiner admits that if Hayzelden et al. discloses a helical coil (which it does not), Hayzelden et al. does not disclose the helical coil having a rectangular cross-sectional configuration and having continuous undulations, wherein the undulations of adjacent turns interlock with each other and wherein the undulations take the form of a sinusoidal wave having positive and negative peaks in which the positive peaks of adjacent turns of coils engage negative peaks of adjacent turns. In an attempt to remedy this deficiency, the Examiner has combined Hayzelden et al. with Klima et al. However, this combination of references does not teach Applicant's invention.

First, Klima et al. is not a steerable guidewire as claimed in Appellant's claim 1. Instead, Klima et al. is a catheter having an open proximal end and a open distal end and it would not be used as a guidewire. Most significantly, while the Examiner contends that Klima et al. discloses positive peaks of adjacent turns of coils engaging negative peaks of adjacent turns, this contention is incorrect. Contrary to the contention by the Examiner, the positive peaks of adjacent turns of the coils of Klima et al. do not engage the negative peaks of adjacent turns. In fact, the adjacent turns of Klima et al.

are expressly separated by a slot 1084 (Figs. 14A-14B) which is filled with the material 90 that forms the outer jacket. Serpentine slot 1084 of Klima et al., which expressly separates the positive peaks of adjacent turns from the negative peaks of adjacent turns is a significant aspect of Klima et al.'s disclosure and is discussed in most detail in column 10, line 64 to column 11, line 21 of Klima et al. It can be seen that Klima et al. actually teaches away from having a positive peaks of adjacent turns of coils engage negative peaks of adjacent turns.

In paragraph 22 of the final rejection, the Examiner misstates that Applicant argued that "Klima et al. teaches away from having positive and negative peaks." Appellant never made this argument as contended by the Examiner. Instead, Appellant urged that the positive peaks of adjacent turns of the coils of Klima et al. do not **engage** the negative peaks of adjacent turns. The Examiner has complete disregarded this critical fact.

In addition to not being a steerable guidewire, and not disclosing a helical coil having continuous undulations taking the form of a sinusoidal wave having positive and negative peaks and in which the positive peaks of adjacent turns of coils engage negative peaks of adjacent turns, Klima et al. does not disclose the elongated deflection member required by claims 1 and 23, or the retaining ribbon required by claims 1 and 23, or the attachment member required by claims 1 and 23. Since Klima et al. discloses an open catheter, an attachment member engaging the distal end of the helical coil, as required by claims 1 and 23, would make no sense.

It is thus submitted that the combination of Hayzelden et al. and Klima et al. is not a proper basis for rejection of Applicant's claims because even if combined, they do not disclose or teach the subject matter claimed in Appellant's claims 1 and 23.

Claims 3-18 are dependent upon claim 1 or on claims that are dependent upon claim 1, and for the reasons that claim 1 is patentable, the dependent claims are also patentable. Claims 25-39 are dependent upon claim 23 or on claims that are dependent upon claims 23, and for the reasons that claim 23 is patentable, the dependent claims are also patentable.

**B. The Rejection of Claims 19, 21, and 22 as Obvious over Hayzelden et al. in view of Klima et al. Should Be Reversed.**

Like independent claim 1, independent claim 19 also concerns a steerable guidewire (with the "steerable guidewire" being referred to in both the preamble and the body of the claim). Like claim 1, claim 19 also calls for a flexible helical coil having a rectangular cross-sectional configuration and having continuous undulations wherein the undulations of adjacent turns interlock with each other, and with the undulations taking the form of a sinusoidal wave having positive and negative peaks and in which the positive peaks of adjacent turns of coils engaged negative peaks of adjacent turns.

As set forth in Section VII A above, neither Hayzelden et al. nor Klima et al. concern a steerable guidewire. Hayzelden et al. concerns an ablation catheter and Klima et al. concerns a catheter having open proximal and distal ends.

As set forth in Section VII A above, Hayzelden et al. does not disclose a flexible helical coil but instead discloses a wire braid which is structurally and functionally significantly different from a helical coil. Further, Klima et al. does not remedy the

deficiencies of Hayzelden et al. because Klima et al. does not disclose a helical coil in which positive peaks of adjacent turns of the coils engage the negative peaks of adjacent turns as claimed in claim 19. As stated above, the adjacent turns of Klima et al. are expressly separated by a slot 1084 (Figs. 14A-14B) which is filled with the material that forms the outer jacket. Thus Klima et al. actually teaches away from having the positive peaks of adjacent turns engaged negative peaks of adjacent turns.

Claim 29 also calls for a rounded bead engaging the distal end of the helical coil of the steerable guidewire. In addition to not being a steerable guidewire or any kind of a guidewire, Klima et al.'s catheter does not having anything resembling a rounded bead engaging the end of a helical coil nor would a rounded bead be appropriate on Klima et al.'s open ended catheter.

Thus the rejection of claim 19 as unpatentable over Hayzelden et al. in view of Klima et al. is inappropriate and should be reversed.

Claims 21 and 22, which are dependent upon claim 19, are patentable for the same reasons that claim 19 is patentable.

## **VIII. CONCLUSION**

The steerable guidewire of the present invention as claimed is significantly different in structure and operation from the ablation catheter and open ended catheter of the prior art applied by the Examiner. The Examiner misconstrued the prior art references and misapplied them to the claims on appeal.

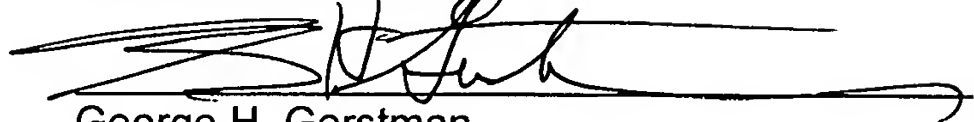
Appellants' claims are focused upon an invention that is a significant improvement upon the prior art, and deserving of patent protection. The references do

not teach Appellants' invention as claimed, and the Board is urged to reverse the Examiner's decision.

Dated: Sept. 26, 2007

Respectfully submitted,

SEYFARTH SHAW LLP

A handwritten signature in black ink, appearing to read "G. Gerstman", is written over a horizontal line.

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## **CLAIMS APPENDIX**

1. A bi-directional steerable guidewire having a deflectable tip which comprises:
  - an elongated flexible tubing having proximal and distal portions;
  - a flexible helical coil having multiple turns and having proximal and distal ends, said helical coil having a rectangular cross-sectional configuration and having continuous undulations wherein the undulations of adjacent turns interlock with each other in order to enhance the rotational rigidity of the coil, the proximal end of said helical coil is attached to the distal portion of the flexible tubing;
  - said undulations are lateral to the length of the elongated flexible tubing;
  - said undulations taking the form of a sinusoidal wave having positive and negative peaks and in which the positive peaks of adjacent turns of coils engage negative peaks of adjacent turns;
  - an elongated deflection member having proximal and distal portions and being slidably disposed within said tubing and within said helical coil, the distal portion of said deflection member being flattened to form a deflection ribbon which extends in a plane;
  - a retaining ribbon for the steerable guidewire having proximal and distal ends, the proximal end of the retaining ribbon is attached to the distal portion of the flexible tubing and the retaining ribbon is oriented to extend in a plane which is generally parallel to the plane of the deflection ribbon; and,
  - an attachment member for the steerable guidewire engaging the distal end of the helical coil, the distal portion of the deflection member and the distal end of the retaining ribbon so that longitudinal movement of the deflection member in a distal direction

causes the distal end of the helical coil to be deflected in one direction and longitudinal movement of the deflection member in a proximal direction causes the distal end of the helical coil to deflect in another opposite direction.

3. A bi-directional steerable guidewire as defined in Claim 1, wherein the continuous undulations take the form of a square sinusoidal wave.

4. A bi-directional steerable guidewire as defined in Claim 1, wherein the helical coil has a square cross-sectional configuration.

5. A bi-directional steerable guidewire as defined in Claim 1, wherein the retaining ribbon and the deflection ribbon are normally biased in an arcuate configuration to thereby cause the distal end of the helical coil to be normally biased in a curved shape.

6. A bi-directional steerable guidewire as defined in Claim 1, wherein the proximal portion of said deflection member is of a circular cross section which extends from the proximal portion of the flexible tubing to approximately the distal portion of the tubing.

7. A bi-directional steerable guidewire as defined in Claim 6, wherein the proximal end of said retaining ribbon extends from the distal portion of the flexible tubing to approximately the distal end of the flexible helical coil.

8. A bi-directional steerable guidewire as defined in Claim 1, wherein the attachment member takes the form of a rounded bead.

9. A bi-directional steerable guidewire as defined in Claim 8, wherein the rounded bead is formed with an epoxy material.



10. A bi-directional steerable guidewire as defined in Claim 1, wherein the attachment member takes the form of a rounded bead which contacts the distal end of the helical coil to define a circular surface at the distal end of the coil and the deflection ribbon engages the rounded bead at a location offset from the center of the circular surface of the rounded bead.

11. A bi-directional steerable guidewire as defined in Claim 10, wherein the distal end of the retaining ribbon engages the rounded bead at a location offset from the center of the circular surface of the rounded bead.

12. A bi-directional steerable guidewire as defined in Claim 11, wherein the distal end of the retaining ribbon engages the rounded bead at a location offset from the center of the circular surface in an opposite direction from the offset location of the deflection ribbon.

13. A bi-directional steerable guidewire as defined in Claim 12, wherein the deflection member and the retaining ribbon are joined to each other within the rounded bead.

14. A bi-directional steerable guidewire as defined in Claim 13, wherein the deflection ribbon and the retaining ribbon are formed as a single unitary element.

15. A bi-directional steerable guidewire as defined in Claim 14, wherein the deflection ribbon and the retaining ribbon are joined to form a generally U-shaped configuration to thereby provide a predetermined spacing between the deflection ribbon and the retaining ribbon and to maintain the deflection ribbon and the retaining ribbon in planes which are parallel to each other.

16. A bi-directional steerable guidewire as defined in Claim 15, wherein the deflection ribbon is formed by flattening an intermediate portion of the deflection member and the retaining ribbon is formed by flattening a distal portion of the deflection member.

17. A bi-directional steerable guidewire as defined in Claim 16, wherein the retaining ribbon is of a thickness which is less than the thickness of the deflection ribbon.

18. A bi-directional steerable guidewire as defined in Claim 17, wherein the deflection ribbon is of a thickness of .002 inches and the retaining ribbon is of a thickness of .0015 inches.

19. A steerable guidewire having a deflectable tip which comprises:  
an elongated flexible member forming the steerable guidewire and having proximal and distal portions;

a flexible helical coil having multiple turns and having proximal and distal ends, said helical coil having a rectangular cross-sectional configuration and having continuous undulations wherein the undulations of adjacent turns interlock with each other in order to enhance the rotational rigidity of the coil, said undulations are lateral to the length of the elongated flexible member; said undulations taking the form of a sinusoidal wave having positive and negative peaks and in which the positive peaks of adjacent turns of coils engage negative peaks of adjacent turns; a proximal end of said helical coil is attached to the distal portion of the elongated flexible member; and,

a rounded bead engaging the distal end of the helical coil of the steerable guidewire.

21. A steerable guidewire as defined in Claim 19, wherein the continuous undulations take the form of a square sinusoidal wave.

22. A steerable guidewire as defined in Claim 19, wherein the helical coil has a square cross-sectional configuration.

23. A steerable guidewire having a deflectable tip which comprises:  
an elongated flexible tubing having proximal and distal portions;  
a flexible helical coil having multiple turns and having proximal and distal ends, said helical coil having a rectangular cross-sectional configuration and having continuous undulations wherein the undulations of adjacent turns interlock with each other in order to enhance the rotational rigidity of the coil, the proximal end of said helical coil is attached to the distal portion of the flexible tubing;  
said undulations are lateral to the length of the elongated flexible tubing;  
said undulations taking the form of a sinusoidal wave having positive and negative peaks and in which the positive peaks of adjacent turns of coils engage negative peaks of adjacent turns;  
an elongated deflection member comprised of proximal and distal portions and being slidably disposed within said tubing and within said helical coil, the proximal portion of the deflection member being of a cylindrical cross section and the distal portion of said deflection member takes the form a deflection ribbon which extends in a plane;

a retaining ribbon for the steerable guidewire having proximal and distal ends, the proximal end of the retaining ribbon is attached to the distal portion of the flexible tubing and the retaining ribbon is oriented to extend in a plane which is generally parallel to the plane of the deflection ribbon; and,

an attachment member for the steerable guidewire engaging the distal end of the helical coil, the distal portion of the deflection member and the distal end of the retaining ribbon so that longitudinal movement of the deflection member in a distal direction causes the distal end of the helical coil to be deflected in one direction and longitudinal movement of the deflection member in a proximal direction causes the distal end of the helical coil to deflect in another opposite direction.

25. A steerable guidewire as defined in Claim 23, wherein the continuous undulations take the form of a square sinusoidal wave.

26. A steerable guidewire as defined in Claim 23, wherein the helical coil has a square cross-sectional configuration.

27. A steerable guidewire as defined in Claim 23, wherein the retaining ribbon and the deflection ribbon are normally biased in an arcuate configuration to thereby cause the distal end of the helical coil to be normally biased in a curved shape.

28. A steerable guidewire as defined in Claim 23, wherein the distal portion of the deflection member and the deflection ribbon are formed from a wire of a circular cross section and in which the distal portion is flattened to form the deflection ribbon.

29. A steerable guidewire as defined in Claim 28, wherein the attachment member takes the form of a rounded bead which contacts the distal end of the helical

coil to define a circular surface at the distal end of the coil and the deflection ribbon engages the rounded bead at a location offset from the center of the circular surface of the rounded bead.

30. A steerable guidewire as defined in Claim 29, wherein the distal end of the retaining ribbon engages the rounded bead at a location offset from the center of the circular surface of the rounded bead.

31. A steerable guidewire as defined in Claim 30, wherein the distal end of the retaining ribbon engages the rounded bead at a location offset from the center of the circular surface in an opposite direction from the offset location of the deflection ribbon.

32. A steerable guidewire as defined in Claim 31, wherein the deflection member and the retaining ribbon are joined to each other within the rounded bead.

33. A steerable guidewire as defined in Claim 32, wherein the deflection ribbon and the retaining ribbon are joined to form a generally U-shaped configuration to thereby provide a predetermined spacing between the deflection ribbon and the retaining ribbon and to maintain the deflection ribbon and the retaining ribbon in planes which are parallel to each other.

34. A steerable guidewire as defined in Claim 33, wherein the deflection ribbon is formed by flattening an intermediate portion of the deflection member and the retaining ribbon is formed by flattening a distal portion of the deflection member.

35. A steerable guidewire as defined in Claim 34, wherein the retaining ribbon is of a thickness which is less than the thickness of the deflection ribbon.

36. A steerable guidewire as defined in Claim 26, wherein the proximal portion of the elongated flexible tubing is coupled to a control handle and the elongated deflection member is mounted with the control handle for longitudinal movement.

37. A steerable guidewire as defined in Claim 36, wherein said control handle includes a movable knob which is coupled to the elongated deflection member for longitudinal positioning of the deflection member.

## **EVIDENCE APPENDIX**

None.

**RELATED PROCEEDINGS APPENDIX**

None.